REMARKS

In the Office Action dated October 2, 2003, claims 1-69 are pending. Claims 1-8, 21-23 and 25-69 are withdrawn from further consideration as drawn to non-elected subject matter. Claims 9-20 and 24 are under consideration. Claims 10, 17, 18, 19, 20 and 24 are rejected under 35 U.S.C. §102(a) as allegedly anticipated by U.S. Patent No. 6,100,048 (the '048 patent). Claims 9, 10, 17, 18, 19, 20 and 24 are rejected under 35 U.S.C. §102(a) as allegedly anticipated by WO 00/27863. Claims 9, 10, 13-20 and 24 are rejected under 35 U.S.C. §112, first paragraph, for allegedly lacking enabling support. Claims 9, 10, 13-20 and 24 are rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to satisfy the written description requirement. Claims 9-20 and 24 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement with respect to the deposited materials. Claims 9, 10, 17-20 and 24 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. The Examiner states that the references accompanying the Information Disclosure Statement (IDS), which Applicants submitted previously, are missing from the file of the application. Additionally, the Examiner has objected to the application for allegedly failing to comply with the requirements of 37 C.F.R. §1.821 through 1.825.

This Response addresses each of the Examiner's rejections and objections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

With respect to the references accompanying the IDS, the Examiner indicates that the record reflects the receipt of the references by the Patent Office on October 29, 2001, yet the references are missing from the file of the application. The Examiner requests that Applicants resubmit the same for consideration by the examiner.

Accordingly, Applicants provide herewith copies of the Information Disclosure Statement, the PTO-FB-A820 Form, and the references, which Applicants mailed on October 29, 2001. In additional, Applicants provide herewith copies of the Supplemental Information

Disclosure Statement, the PTO-FB-A820 Form, and the references, which Applicants mailed on April 1, 2002.

The Examiner has objected to the application for allegedly failing to comply with the requirements of 37 C.F.R. §1.821 through 1.825. Specifically, the Examiner points out that the specification makes reference to sequences on page 16, line 12, without sequence identifiers.

Applicants have amended the specification to insert the sequence identifiers (SEQ ID NOS: 7-10) in the paragraph beginning on page 16, line 12. Applicants also provide herewith a paper copy and a computer-readable copy of the substitute Sequence Listing which now includes SEQ ID NOS: 7-10, as well as a Statement as required by 37 C.F.R. §1.821(f). No new matter is introduced by the substitute Sequence Listing. As such, withdrawal of the objection to the specification is therefore respectfully requested.

Claims 1-8, 21-23 and 25-69 are withdrawn from further consideration as drawn to non-elected subject matter. Applicants have canceled claims 1-8, 21-23 and 25-69 by way of the instant amendment. Applicants reserve the right to file a divisional application to pursue the non-elected subject matter.

Claims 10, 17-20 and 24 are rejected under 35 U.S.C. §102(a) as allegedly anticipated by U.S. Patent No. 6,100,048 (the '048 patent).

The '048 patent discloses a polynucleotide which, according to the Examiner, shares 79% sequence identity with instant SEQ ID NO: 2 over a region of about 1500 base pairs and would thus be expected to hybridize to instant SEQ ID NO: 2 under the conditions required by the claims as highly stringent, absent evidence to the contrary. Further according to the Examiner, the polynucleotide disclosed by the '048 patent encodes a polypeptide that is a functional melantocortin-4 receptor. In addition, the Examiner refers to col. 15, Example 15 of the '048 patent where vectors, host cells and methods of producing the polypeptide are allegedly disclosed.

By way of the instant amendment, Applicants have canceled independent claim 10 without prejudice. Dependent claims 17-20 have been amended to delete the references to

claims 1-10. Claims 17-20 and 24, as presently amended, depend upon claims 11-16 and new claims 70-71. The Examiner apparently recognizes that the nucleic acids of claims 11-16 are not disclosed in the '048 patent, because claims 11-16 are not included in the §102(a) rejection. New claims 70-71 are drawn to nucleic acid molecules consisting of a nucleotide sequence coding for the specified fragments of canine melantocortin-4 receptor. The nucleic acids of claims 70-71 are also not disclosed in the '048 patent. Therefore, it is respectfully submitted that claims 17-20 and 24, as amended, are not anticipated by the '048 patent. Withdrawal of the rejection based on the '048 patent is therefore respectfully requested.

Claims 9-10, 17-20 and 24 are rejected under 35 U.S.C. §102(a) as allegedly anticipated by WO 00/27863.

WO 00/27863 discloses a polynucleotide which, according to the Examiner, shares 87% sequence identity with instant SEQ ID NO: 2 over a region of about 1000 base pairs and would thus be expected to hybridize to instant SEQ ID NO: 2 under the conditions required by the claims as highly stringent, absent evidence to the contrary. Further according to the Examiner, the polynucleotide disclosed by WO 00/27863 encodes a polypeptide that is a functional rhesus monkey melantocortin-4 receptor. In addition, the Examiner states that vectors, host cells and methods of producing the polypeptide are disclosed in WO/00/27863.

By way of the instant amendment, Applicants have canceled independent claims 9-10 without prejudice. Claims 17-20 and 24, as presently amended, depend upon claims 11-16 and new claims 70-71. The Examiner apparently recognizes that the nucleic acids of claims 11-16 are not disclosed in WO 00/27863, because claims 11-16 are not included in the §102(a) rejection. New claims 70-71 are drawn to nucleic acid molecules consisting of a nucleotide sequence coding for the specified fragments of canine melantocortin-4 receptor. The nucleic acids of claims 70-71 are also not disclosed in WO 00/27863. Therefore, it is respectfully submitted that claims 17-20 and 24, as amended, are not anticipated by WO 00/27863. Withdrawal of the rejection based on WO 00/27863 is therefore respectfully requested.

Claims 9, 10, 13-20 and 24 are rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enabling support.

The Examiner acknowledges that the specification is enabling for polynucleotides encoding polypeptides of SEQ ID NOS: 3 or 4, and fragments thereof, and fragments thereof fused with additional heterologous sequences, e.g., epitope tags or carrier proteins. However, the Examiner contends that the specification does not reasonably provide enablement for nucleic acid molecules which encode polypeptides comprising only portions of SEQ ID NO: 3 or 4 (as in claims 15-16), or which need only share a percent identity with, or hybridize under the recited conditions to, the encoding polynucleotides. The Examiner alleges that the specification has not provided guidance as to what properties of the allelic variants or sequence variants of the protein corresponding to SEQ ID NO: 4 might be desired, nor any guidance as to which amino acid substitutions, deletions or insertions to make in order to achieve any desired property. Thus, the Examiner concludes that it would require undue experimentation for the skilled artisan to make and/or use the claimed invention in its full scope.

Applicants respectfully submit that claims 9-10 have been canceled without prejudice, thereby rendering the rejection thereof moot. Claims 13-20 and 24, as amended, are drawn to nucleic acid molecules which comprise a sequence having specified identity to certain recited sequences and which encode "a functional melantocortin-4 receptor".

As described in the specification on page 15, lines 16-18, a functional melantocortin-4 receptor binds to melantocortin-4 receptor ligand or ligand analogs. Whether a polypeptide is a functional melantocortin-4 receptor can be determined by *in vitro* ligand binding assays, as explicitly illustrated in the specification, at page 24, line 25 through page 25, line 19, and pages 52-55 (Examples 2-3), for example. Applicants further respectfully submit that the specification also provides adequate teaching as to what types of changes can be made to the amino acids in order to maintain the biological activity of the melantocortin-4 receptor. See, e.g., page 15, lines 8-16. Thus, based on the present teaching, those skilled in the art would be able to make a nucleic acid molecule having specified identity to a particular nucleotide sequence and determine

whether such molecule has the desired property, i.e., "encoding a functional melantocortin-4 receptor", as recited in claims 13-16, without undue experimentation.

Added claims 70-71 are drawn to nucleic acid molecules consisting of a nucleotide sequence coding for the specified fragments of canine melantocortin-4 receptor. The Examiner has acknowledged that the specification provides enablement for such subject matter.

Accordingly, the rejection of claims 9, 10, 13-20 and 24 under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement, is overcome. Withdrawal of the rejection is therefore respectfully requested.

Claims 9, 10, 13-20 and 24 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner states that the specification merely discloses a feline and a canine polynucleotide of SEQ ID NO: 1 and 2, respectively, and yet the claims encompass polynucleotides not adequately described in the specification including polynucleotides from other species, mutated sequences, allelic variants, and sequences need that need only hybridize to SEQ ID NO: 1 or 2 under the recited conditions or share a percent identity.

Applicants respectfully submit that the rejection of claims 9-10 is rendered moot in view of cancellation of these claims. Claims 13-20 and 24, as amended, are drawn to nucleic acid molecules which comprise a sequence having a specified identity to certain recited sequences and which encode "a functional melantocortin-4 receptor".

Applicants further respectfully submit that the written description requirement of 35 U.S.C. §112, first paragraph, does not require actual reduction to practice of every aspect of the claimed invention. In the instant case, the specification specifically describes two nucleic acid species (feline and canine melantocortin-4 receptor genes), as well as the functional and structural characteristics of other polynucleotide species within the claimed genus. That is, the nucleic acid molecules, as presently claimed, are described both structurally by way of the

sequence identity to specified sequences, and functionally by way of the encoded polypeptide (i.e., " a functional melantocortin-4 receptor"). As discussed above, the specification adequately describes how to make variations to the nucleic acid molecules while retaining the biological activities of the encoded protein. Therefore, Applicants respectfully submit that the instant claims satisfy the written description requirement of 35 U.S.C. §112, first paragraph. Withdrawal of the rejection is therefore respectfully requested.

Claims 9-20 and 24 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement with respect to the deposited materials. The Examiner points out that there is no indication in the specification as to the public availability of the deposited material, ATCC #s PTA-1762 and PTA-1761. In addition, the Examiner indicates that the date of the deposit and the address of the depository are missing on page 16 of the specification.

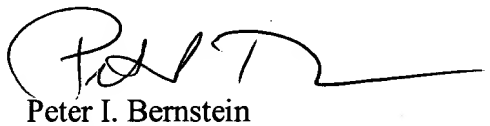
Applicants have amended the paragraph beginning on page 16, line 10 to insert the information regarding the deposit. A copy of the receipt of the ATCC deposit is also provided herewith. Applicants further submit that all restrictions on availability of the deposited materials to the public will be irrevocably removed upon the granting of the patent based upon the captioned application and the deposited materials will remain permanently available for a term of at least 5 years after the most recent request for the furnishing of a sample, and in any case, for a period of at least 30 years after the date of deposit or for the enforceable life of the U.S. patent whichever is longer. In the event that the deposited materials become non-viable or are inadvertently destroyed, such will be replaced with viable materials of the same taxonomic description. As such, it is respectfully submitted that the rejection under 35 U.S.C. §112, first paragraph, for failing to comply with the enablement requirement with respect to the deposited materials, is overcome. Withdrawal of the rejection is therefore respectfully requested.

Claims 9, 10, 17-20 and 24 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for reciting a "functional MC4R".

Applicants respectfully submit that the claims, as presently amended, recite "a functional melantocortin-4 receptor". The meaning of this term is clear in light of the specification, e.g., the description on page 15, lines 16-18. Whether a polypeptide is a functional melantocortin-4 receptor can be determined by *in vitro* ligand binding assays, as illustrated in the specification, at page 24, line 25 through page 25, line 19, and pages 52-55 (Examples 2-3), for example. Therefore, the claims as presently recited are not indefinite. Withdrawal of the rejection is therefore respectfully requested.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



Peter I. Bernstein
Registration No. 43,497

Scully, Scott, Murphy & Presser
400 Garden City Plaza
Garden City, New York 11530
516-742-4343
XZ:ab

Encls.:
- Copy of the Receipt of the ATCC Deposits;
- Copies of IDS, PTO-FB-A820 Forms and the references submitted on October 29, 2001(109 references) and on April 1, 2002 (5 references);
- Substitute paper and computer readable copy of the substitute Sequence Listing; and
- Statement.

RECEIPT OF THE ATCC DEPOSITS

PC10743

ATCC

10801 University Blvd • Manassas, VA 20110-2209 • Telephone: 703-365-2700 • FAX: 703-365-2745

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Pfizer, Inc.
Attn: Dr. L. H. Huang
Central Research
Eastern Point Road
Groton, CT 06340

Deposited on Behalf of: Pfizer, Inc.

Identification Reference by Depositor:	**Patent Deposit Designation**
Escherichia coli (DH5∝) transformed with pCMV-SPORT6.0/ Canine MC4R: UC 25427	PTA-1761
Escherichia coli (DH5∝) transformed with pCMV-SPORT6.0/ Feline MC4R: UC 25428	PTA-1762

The deposits were accompanied by: __ a scientific description _ a proposed taxonomic description indicated above. The deposits were received April 25, 2000 by this International Depository Authority and have been accepted.

AT YOUR REQUEST: X We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested May 3, 2000. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

Barbara E. Coupé

Barbara E. Coupé, Administrator, Patent Depository **Date: May 5, 2000**

cc: Dr. P. C. Richardson (Ref: Docket or Case No.: PC10743)

BP/49